

Confidential

MP Vial Adapter 13mm

Traditional 510(k)

510(k) Summary**1. Submitter Information**

Name: Medimop Medical Projects Ltd
Address: 17 Hatidhar St
Ra'anana 4366519
Israel
Telephone Number: 972-9-7778666
Fax Number: 972-9-7485916

Contact person: Ilanit Goldgraber
Director of RA
Telephone Number: 972-9-7778666 Extension 219
Fax Number: 972-9-7485916
E-mail: ilanit.goldgraber@westpharma.com

US Agent: Deborah M. Thomas
West Pharmaceutical Services, Inc.
Address: 530 Herman O. West Drive
Exton, PA 19341-1147
Telephone Number: (610) 594-3105
Fax Number: (610) 594-3004
Email: debbie.thomas@westpharma.com
Date Prepared: 23 January 2013

AUG 08 2013

2. Device Name

Device Trade Name: MP Vial Adapter 13mm
Common Name: MP Vial Adapter 13mm
Classification name: IV Administration Set

3. Classification

Product Code: LHI
Regulation No.: 880.5440
Class: II
Panel identification: General Hospital Panel

4. Predicate Devices

- Mixject with Spray Head (K122023)
- Mixject Dispensing Pin 13mm (K963583)
- Q-Cap needle-Free Reconstitution 13mm Vial Adapter (K043304)

5. Device description

The device is a needless transfer device which enables reconstitution of one diluent vial and up to five vials of the fertility drugs Bravelle[®], or Menopur[®] manufactured by Ferring using one MP Vial Adapter 13 mm.

The device is a single use sterile device which will be included into Ferring Pharmaceutical's Bravelle[®] and/or Menopur[®] drug kits to assist in the reconstitution of these lyophilized drugs for injection using one reconstitution diluent vial.

6. Indications for use

Allow needle-free withdrawal, reconstitution and transfer of Bravelle[®] (urofolitropin for injection, purified) and/or Menopur[®] (menotropins for injection, USP) and diluent from vials into an injection syringe for administration on a single patient during a single procedure.

7. Technological Characteristics and Substantial Equivalence

The MP Vial Adapter 13mm material of construction and design is the vial adapter sub-component of the previously cleared Medimop Mixject with spray head (K122023). The proposed devices performance, packaging and sterilization are the same to that of a previously cleared Medimop 13mm Dispensing Pin (Vial Adapter - K963583). The only

change to the proposed device is the indication for use which is being updated for use with the Ferring Pharmaceutical's fertility drugs Bravelle® and/or Menopur® and is equivalent to that of the previously cleared Q-Cap (K043304) and is therefore substantially equivalent to the predicate devices.

8. Nonclinical Testing

Bench testing was performed to demonstrate the ability of the proposed MP Vial Adapter 13mm to effectively reconstitute and transfer Bravelle® and/or Menopur® fertility drugs.

9. Conclusion

Comparative analysis of technological characteristics between proposed and predicate devices and results of verification testing performed demonstrate that the subject device is substantially equivalent to the legally marketed predicate devices. Any differences between the proposed and predicate devices do not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

August 08, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Medimop Medical Projects, Limited
Mr. Ilanit Goldgraber
Director of Regulatory Affairs
17 Hatidhar Street
RA'ANANA ISRAEL 4366519

Re: K130179
Trade/Device Name: MP Vial Adapter 13 mm
Regulation Number: 21 CFR 880.5440
Regulation Name: Set, I.V. Fluid Transfer
Regulatory Class: II
Product Code: LHI
Dated: June 12, 2013
Received: July 11, 2013

Dear Mr. Goldgraber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kwame O. Ulmer -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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MP Vial Adapter 13mm

Traditional 510(k)

Indications for Use

510(k) Number (if known): K130179

Device Name: MP Vial Adapter 13 mm

Indications for Use:

Allow needle-free withdrawal, reconstitution and transfer of Bravelle® (urofolitropin for injection, purified) and/or Menopur® (menotropins for injection, USP) and diluent from vials into an injection syringe for administration on a single patient during a single procedure.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C.
Chapman

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23 January 2013

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